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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/470,009	LEE ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-26, 51, 53, 56-60, 65 and 66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-26, 51, 53, 56-60, 65 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 11, 13-18, 19, 21-26, 50, 51, 53, 56-60, 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard, 5,242,396, in view of Crowley et al., 6,004,279, and further in view of Berenstein et al., 5,895,378.

Evard discloses the invention substantially as claimed.

More specifically, as to claim 11, Evard discloses a mandrel (26) comprised of a variable stiffness, non-metal material (i.e., plastic, see column 3, lines 38-42, and column 4, lines 28-30) said mandrel uniformly tapered from a proximal section to a distal section (see column 3, lines 38-42, and Figure 1), and said mandrel adapted to reinforce a catheter (see Figure 1.)

As to claim 19, Evard discloses an outer member (17); a hollow inner member (14) extending through said outer member; an outer lumen (18) between said inner and outer members; and a mandrel extending through said outer lumen, said mandrel comprised of a variable stiffness material, said mandrel uniformly tapered, see column

3, lines 38-42, from a proximal section to a distal section and said mandrel is adapted to reinforce said catheter (see Figure 1.)

As to claims 13, 21 and 56, a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel, see Figure 1.

As to claims 14 and 22, the catheter comprises an inflatable member (12, 22 and 23) comprising a proximal portion (i.e., proximal portion of 23) and a distal portion (i.e., portion of balloon that includes distal portion of 23), wherein said distal section of said mandrel (26) extends past said proximal portion of said inflatable member, see Figure 1. (Applicant has not defined in the claims where the proximal portion and distal portion of the inflatable member begins and ends.)

As to claims 15, 23 and 53, said distal section of said mandrel (26) extends past said distal portion (i.e., portion of balloon that includes distal portion of 23) of said inflatable member, see Figure 1.

As to claims 16, 24 and 45, said mandrel (26) is capable of being formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

As to claims 17 and 25, said mandrel (26) is capable of being formed by necking at high temperatures such that said proximal section is stiffer than said distal section.

As to claims 18, 26 and 51 said mandrel (26) is capable of being formed by taper extruding such that said proximal section is stiffer than said distal section.

As to claims 57, 59, and 65, the mandrel is fixed to the catheter shaft (see column 3, lines 38-39.)

As to claims 58, 60, 64, and 66, an inner tubular member (14) is disposed near the mandrel, wherein the inner tubular member is adapted to receive a guidewire (see column 3, lines 21-26.)

However, Evard does not discloses that the proximal section has a first crystallinity and the distal section has a second crystallinity lower than the proximal section first crystallinity such that the proximal section is stiffer.

Crowley teaches a guidewire wherein the distal portions are annealed progressively to cause the distal portions to be more flexible than proximal portions (column 2, lines 6-10.) However, Crowley does not teach that the guidewire distal or proximal portions are formed from a non-metal material. Examiner emphasizes that a guidewire provides substantially the same function as a mandrel in that both provide rigidity to a catheter to enable a catheter to be inserted in a patient.

Berenstein teaches that where a catheter is formed from PVC or a polyurethane, the catheter is provided with added flexibility where the catheter is annealed (column 5, line 58 – column 6, line 4.)

Thus, Crowley teaches that it would be desirable to provide gradual flexibility to a guidewire by annealing a guidewire. Berenstein teaches that a non-metal such as PVC or a polyurethane can be annealed to make the material more flexible.

The Evard mandrel is formed from a plastic material (column 4, line 30), and the PVC or polyurethane in the Berenstein reference are plastic materials. Berenstein teaches that PVC or polyurethane can be annealed to provide flexibility. Crowley teaches that distal portions of a guidewire can be annealed in order to provide gradual

flexibility to a guidewire as would be desirable for medical applications. It would have been obvious to anneal the distal portions of the Evard plastic mandrel, as taught by Crowley in view of Berenstein, in order to provide gradual flexibility to a catheter as would be desirable as taught by Crowley. Annealing provides the proximal section with a higher crystallinity than the distal section.

2. Claims 11, 13, 16-18, 51 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shank et al., 5,147,317, in view of Crowley et al., 6,004,279, and further in view of Berenstein et al., 5,895,378.

Shank discloses the invention substantially as claimed.

More specifically, Shank et al. discloses a mandrel (10) comprised of a variable stiffness, non-metal material, see column 7, line 5, said mandrel uniformly tapered (34) from a proximal section to a distal section, and said mandrel adapted to reinforce a catheter.

As to claims 13, and 56, a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel, see Figure 2.

As to claim 16, said mandrel (10) is capable of being formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

As to claim 17, said mandrel (10) is capable of being formed by necking at high temperatures such that said proximal section is stiffer than said distal section.

As to claims 18, 43, and 51 said mandrel (10) is capable of being formed by taper extruding such that said proximal section is stiffer than said distal section.

However, Shank does not discloses that the proximal section has a first crystallinity and the distal section has a second crystallinity lower than the proximal section first crystallinity such that the proximal section is stiffer.

Crowley teaches a guidewire wherein the distal portions are annealed progressively to cause the distal portions to be more flexible than proximal portions (column 2, lines 6-10.) However, Crowley does not teach that the guidewire distal or proximal portions are formed from a non-metal material.

Berenstein teaches that where a catheter is formed from PVC or a polyurethane, the catheter is provided with added flexibility where the catheter is annealed (column 5, line 58 – column 6, line 4.)

Thus, Crowley teaches that it would be desirable to provide gradual flexibility to a guidewire by annealing a guidewire. Berenstein teaches that a non-metal such as PVC or a polyurethane can be annealed to make the material more flexible.

The Shank guidewire is formed from a plastic material (column 7, line 5), and the PVC or polyurethane in the Berenstein reference are plastic materials. Berenstein teaches that PVC or polyurethane can be annealed to provide flexibility. Crowley teaches that distal portions of a guidewire can be annealed in order to provide gradual flexibility to a guidewire as would be desirable for medical applications. It would have been obvious to anneal the distal portions of the Shank plastic guidwire, as taught by Crowley in view of Berenstein, in order to provide gradual flexibility to a catheter as

would be desirable as taught by Crowley. Annealing provides the proximal section with a higher crystallinity than the distal section.

3. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hibbs et al., 4,950,257, in view of Crowley et al., 6,004,279, and further in view of Berenstein et al., 5,895,378.

Hibbs discloses the invention substantially as claimed.

More specifically, Hibbs et al. discloses a mandrel (20), comprised of a variable stiffness, non-metal material, said mandrel uniformly tapered from a proximal section to a distal section, and said mandrel adapted to reinforce said catheter. The material is polyamide, see column 2, line 16.

Hibbs discloses that a flexible tip is desirable (column 2, line 42.)

However, Hibbs does not discloses that the proximal section has a first crystallinity and the distal section has a second crystallinity lower than the proximal section first crystallinity such that the proximal section is stiffer.

Berenstein teaches that where a catheter is formed from PVC or a polyurethane, the catheter is provided with added flexibility where the catheter is annealed (column 5, line 58 – column 6, line 4.)

Crowley teaches a guidewire wherein the distal portions are annealed progressively to cause the distal portions to be more flexible than proximal portions (column 2, lines 6-10.)

Thus, Berenstein teaches that a plastic catheter can be annealed to provide flexibility. Crowley teaches that annealing progressively distal portions would provide gradual flexibility toward the distal end. It would have been obvious that progressively annealing distal portions of the Hibbs mandrel would provide a flexible distal tip portion, as would be desirable for a catheter assembly as taught by Hibbs as well as Crowley.

4. Claim 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard, 5,242,396, in view of Crowley et al., 6,004,279, and further in view of Berenstein et al., 5,895,378, as applied to claim 11, and further in view of Maguire et al., 6,599,288.

Evard in view of Crowley and further in view of Berenstein disclose the invention substantially as claimed, (see above under section 1), except for the material being specifically polyimide.

Maguire et al. discloses a catheter with a mandrel made of polyimide material (see column 58, lines 35-40.) Maguire et al. also discloses that polyimide is a rigid material (see column 53, lines 24-28.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Evard mandrel from a high strength plastic, such as polyimide, as taught by Maguire et al. because Maguire shows that polyimide is a well known rigid material used in mandrels, such as the mandrel of Evard.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chen et al., 4,536,533, discloses that crystallinity in polamides is desirable to maximize stiffness (column 1, lines 20-24). Broyer, 5,294,395, discloses that a monofilament for sutures can be annealed to further increase crystallinity. Harvie, 5418,308, discloses that annealing polymers leads to higher crystallinity (column 7, lines 19-22.)

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
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